Reporting Adverse Reactions: **MedWatch Form FDA 3500A**

Jacque Polder, BSN, MPH
Su Wang, MD MPH
FDA
Centers for Biologics Evaluation and Research (CBER)
Office of Biostatistics and Epidemiology
Therapeutics and Blood Safety Branch

MedWatch and HCT/P Safety

- With MedWatch, FDA can detect trends across the country that may not be identified at an individual site.

- Goal of HCT/P surveillance is to prevent additional adverse reactions.

It is a reportable HCT/P adverse reaction, now what do I do?

- You have **15 days** from receipt of information

- Use Form FDA 3500A (MedWatch)

Obtain from CBER or electronically from:
www.fda.gov/medwatch or www.hhs.gov/forms

MedWatch forms: http://www.fda.gov/medwatch/

U.S. Food and Drug Administration

Department of Health and Human Services

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MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

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Welcome to MedWatch, your Internet gateway for timely safety information on the drugs and other medical products regulated by the U.S. Food and Drug Administration.

What's New

Cordarone (amiodarone HCl) - New Medication Guide issued, to be provided with each prescription dispensed to patients.
(Posted 01/10/2005)

Avastin (bevacizumab) - WARNINGS, PRECAUTIONS, ADVERSE EVENTS, and DOSAGE AND ADMINISTRATION sections of labeling updated to describe arterial thromboembolic events when Avastin is used in combination with intravenous 5-fluorouracil–based chemotherapy.
(Posted 01/06/2005)

American Health & Herbs Ministry Eye Rinse Products - Voluntary recall

Safety Information

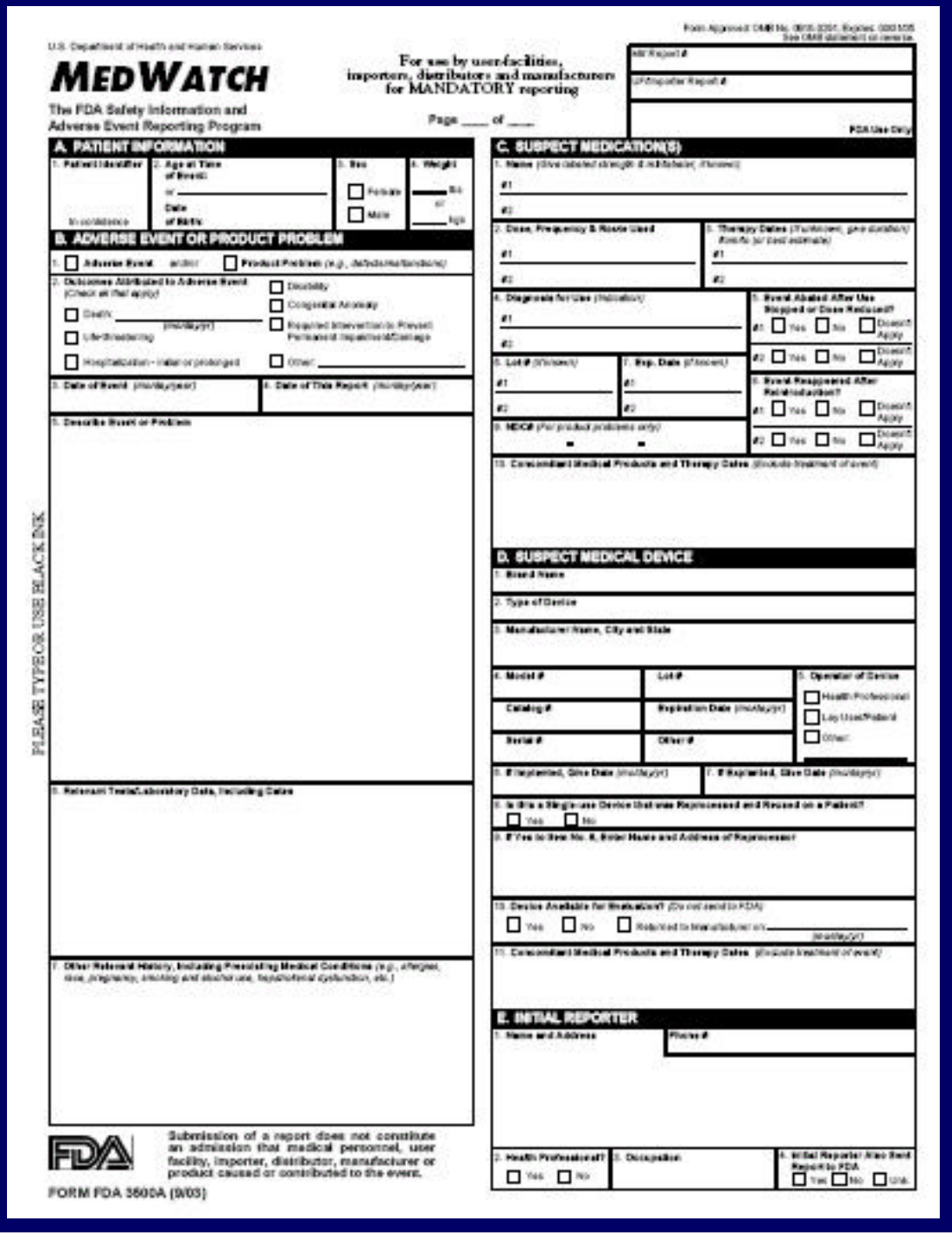
Medical Product Reporting

Reporting Adverse Reactions with MedWatch:

Form FDA 3500A

(3500 for Voluntary)

Page 1



U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

For use by user facilities, importers, distributors and manufacturers for MANDATORY reporting

Page ___ of ___

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier
2. Age at Time of Event: or Date of Birth
3. Sex: Female, Male
4. Weight: lbs or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. Adverse Event, Product Problem (e.g., defect/malfunction)
2. Outcomes Attributed to Adverse Event (Check all that apply): Death (mm/dd/yyyy), Life-threatening, Hospitalization - initial or prolonged, Disability, Congenital Anomaly, Required Intervention to Prevent Permanent Impairment/Damage, Other:
3. Date of Event (mm/dd/yyyy)
4. Date of This Report (mm/dd/yyyy)
5. Describe Event or Problem
6. Relevant Tests/Laboratory Data, Including Dates
7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney dysfunction, etc.)

C. SUSPECT MEDICATION(S)

1. Name (Give labeled strength & manufacturer)
2. Dose, Frequency & Route Used
3. Therapy Dates (mm/dd/yy, give duration)
4. Diagnosis for Use (Indication)
5. Event Abated After Use Stopped or Dose Reduced?
6. Lot #
7. Exp. Date
8. Event Reappeared After Reintroduction?
9. NDC# (For product problems only)
10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

D. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Type of Device
3. Manufacturer Name, City and State
4. Model #, Lot #, Catalog #, Expiration Date (mm/dd/yy), Serial #, Other #
5. Operator of Device: Health Professional, Lay User/Patient, Other:
6. If Implanted, Give Date (mm/dd/yy)
7. If Explanted, Give Date (mm/dd/yy)
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor
10. Device Available for Evaluation? (Do not send to FDA)
11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

E. INITIAL REPORTER

1. Name and Address
Phone #
2. Health Professional?
3. Occupation
4. Initial Reporter Also Sent Report to FDA

PLEASE TYPE OR USE BLACK INK

FDA

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

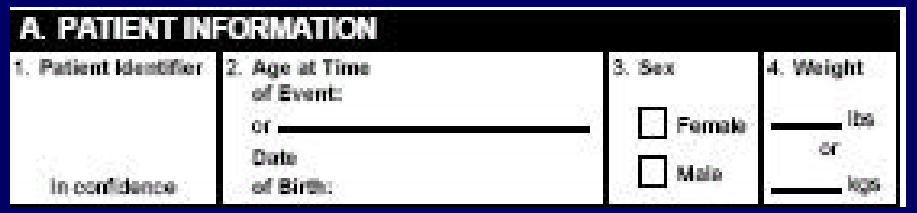
FORM FDA 3500A (9/03)

MedWatch Form FDA 3500A

Page 1

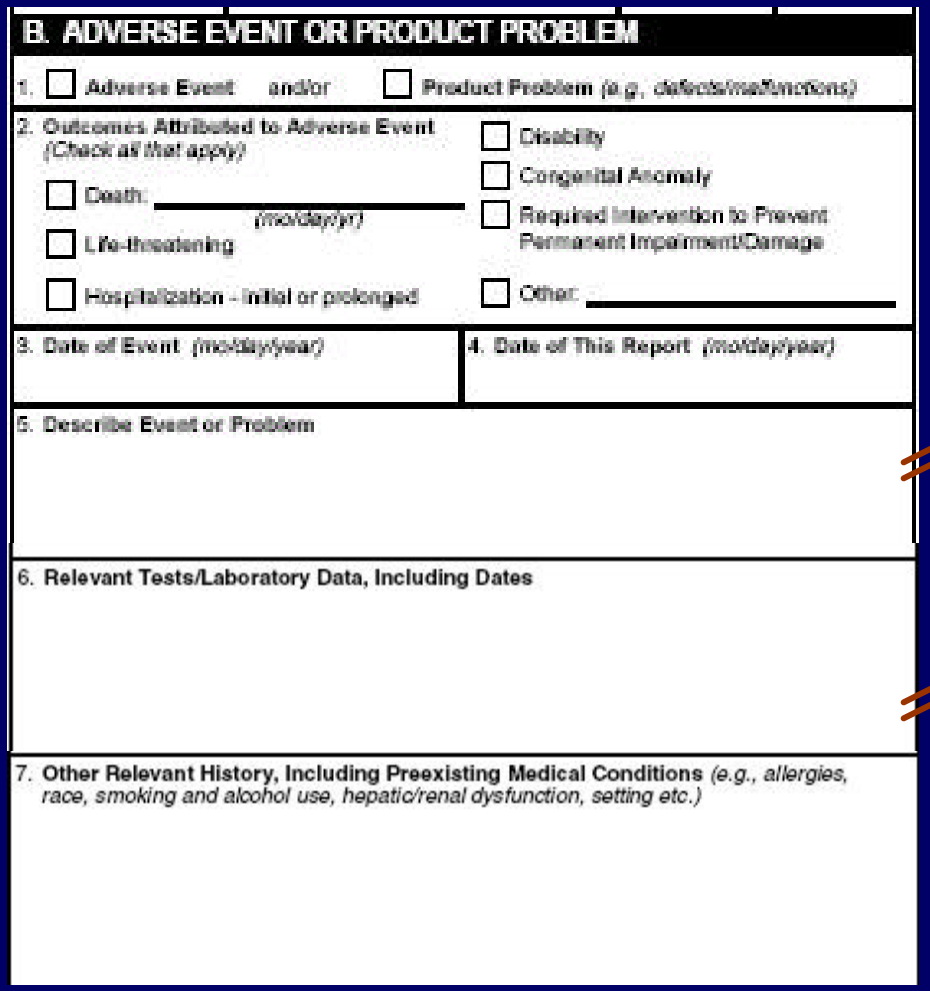
Section A: Patient Information

Section B: Adverse Event, Product Problem or Error



A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: or Date of Birth:	3. Sex	4. Weight
In confidence		☐ Female ☐ Male	____ lbs or ____ kgs



B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☐ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: _____ *(mo/day/yr)*
- ☐ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Disability
- ☐ Congenital Anomaly
- ☐ Required Intervention to Prevent Permanent Impairment/Damage
- ☐ Other: _____

3. Date of Event *(mo/day/year)*

4. Date of This Report *(mo/day/year)*

5. Describe Event or Problem

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, smoking and alcohol use, hepatic/renal dysfunction, setting etc.)*

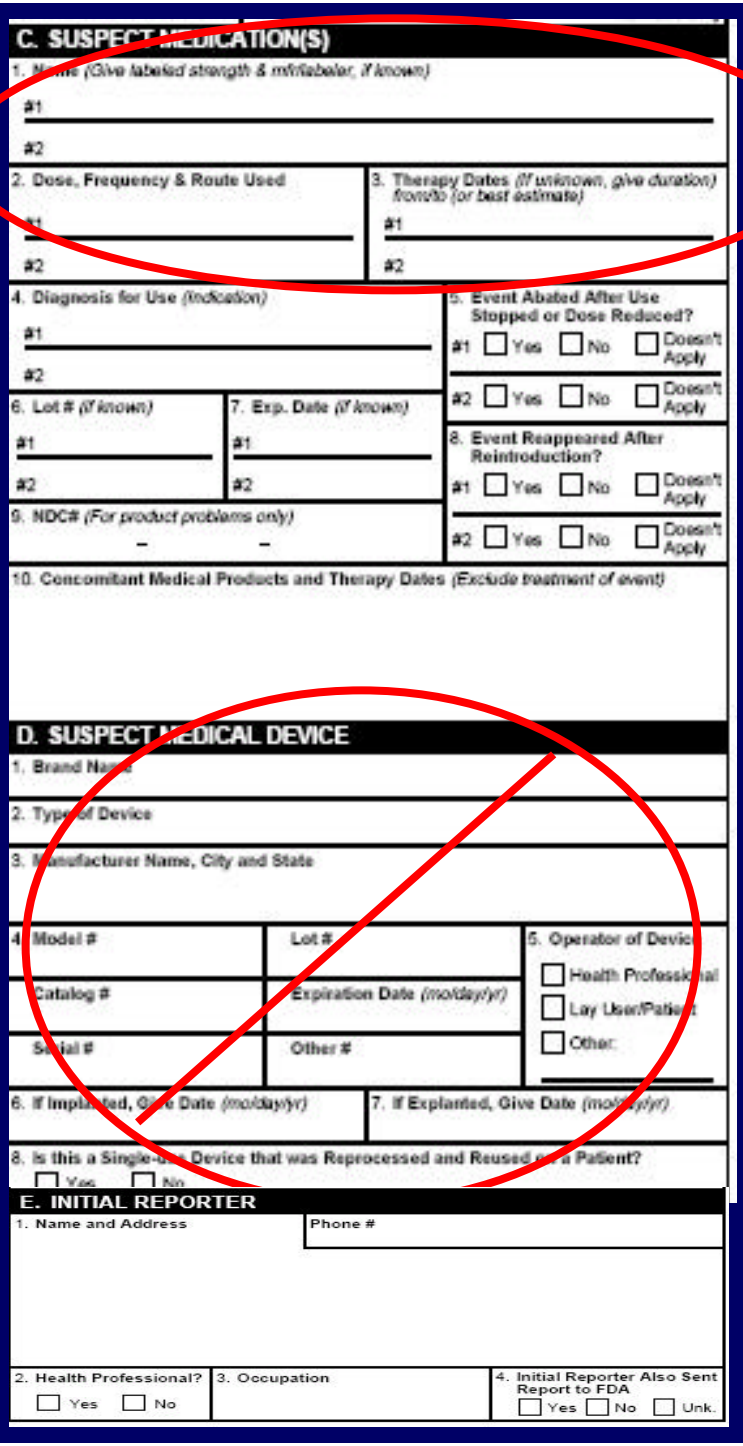
MedWatch Form FDA 3500A **Page 1**

For HCTP's:

Use **Section C** for **Suspect Medication(s)**

not

Section D for Suspect Device



Filling out Section C. for an HCT/P

C1. **Name, manufacturer**

C3. **Dates of Use:**

#1 ***Date of implant***

#2 Date of explant, *if applies*

C4. **Diagnosis or Reason for use**

C6. **Lot #**

C7. **Expiration #**

C10. **Concomitant Medical Products**

C. SUSPECT MEDICATION(S) Section C - Help

1. **Name** *(Give labeled strength & mfr/labeler, if known)*
   - #1 Tibialis Tendon Jointsave Company
   - #2
2. **Dose, Frequency & Route Used**
   - #1
   - #2
3. **Therapy Dates** *(If unknown, give duration) from/to (or best estimate)*
   - #1 11/9/04
   - #2 11/30/04
4. **Diagnosis for Use** *(Indication)*
   - #1 ACL repair
   - #2
5. **Event Abated After Use Stopped or Dose Reduced?**
   - #1 ☐ Yes ☐ No ☐ Doesn't Apply
   - #2 ☐ Yes ☐ No ☐ Doesn't Apply
6. **Lot #** *(if known)*
   - #1 AZ2004-1264
   - #2
7. **Exp. Date** *(if known)*
   - #1 08/05
   - #2
8. **Event Reappeared After Reintroduction?**
   - #1 ☐ Yes ☐ No ☐ Doesn't Apply
   - #2 ☐ Yes ☐ No ☐ Doesn't Apply
9. **NDC#** *(For product problems only)*
   - - -
10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*

Cephalexin 500 mg po bid 11/23-11/30/04

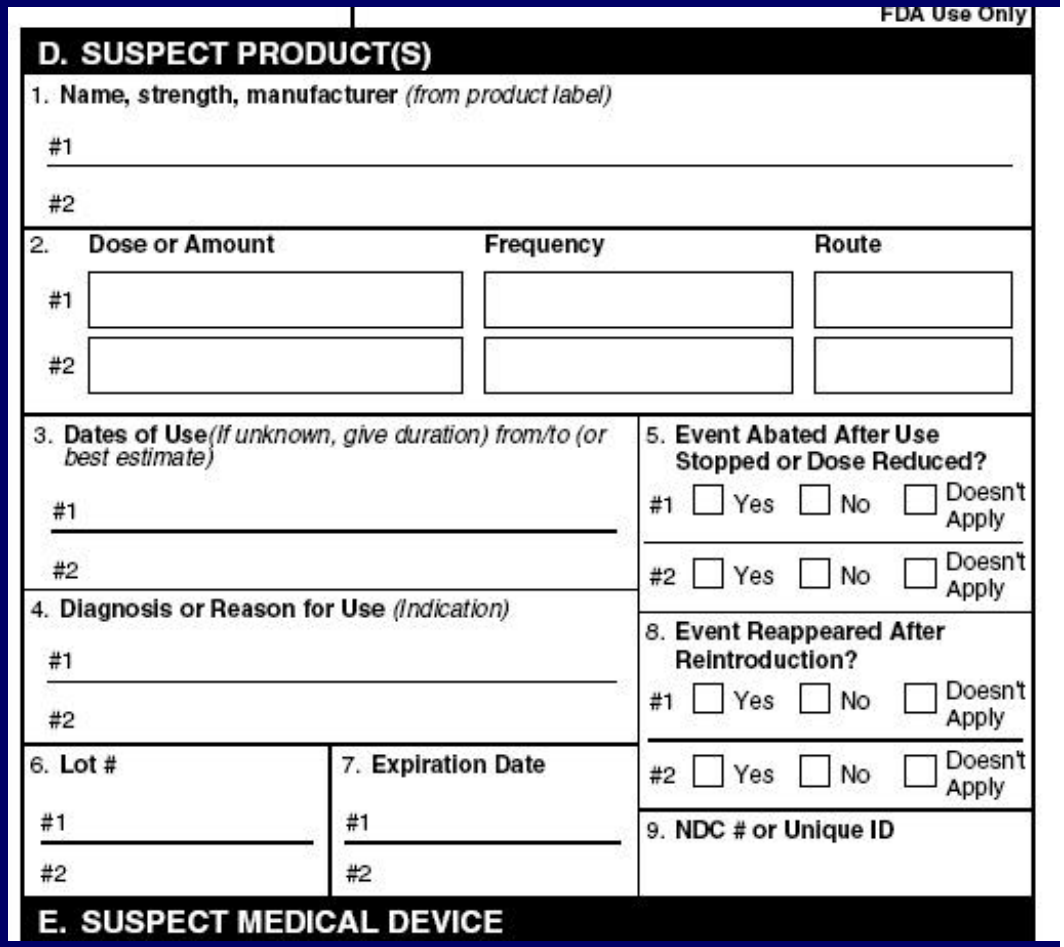
(C2, C5, C8, C9 are not relevant for HCT/P's)

Proposed MedWatch 3500A

Changes in this section:

Section **D.**
Suspect PRODUCT(S)

D9. NDC# or Unique ID



FDA Use Only

D. SUSPECT PRODUCT(S)

1. **Name, strength, manufacturer** *(from product label)*

#1

#2

2.	Dose or Amount	Frequency	Route
#1			
#2			

3. **Dates of Use** *(If unknown, give duration) from/to (or best estimate)*

#1

#2

4. **Diagnosis or Reason for Use** *(Indication)*

#1

#2

5. **Event Abated After Use Stopped or Dose Reduced?**

#1 ☐ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. **Event Reappeared After Reintroduction?**

#1 ☐ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**

#1

#2

7. **Expiration Date**

#1

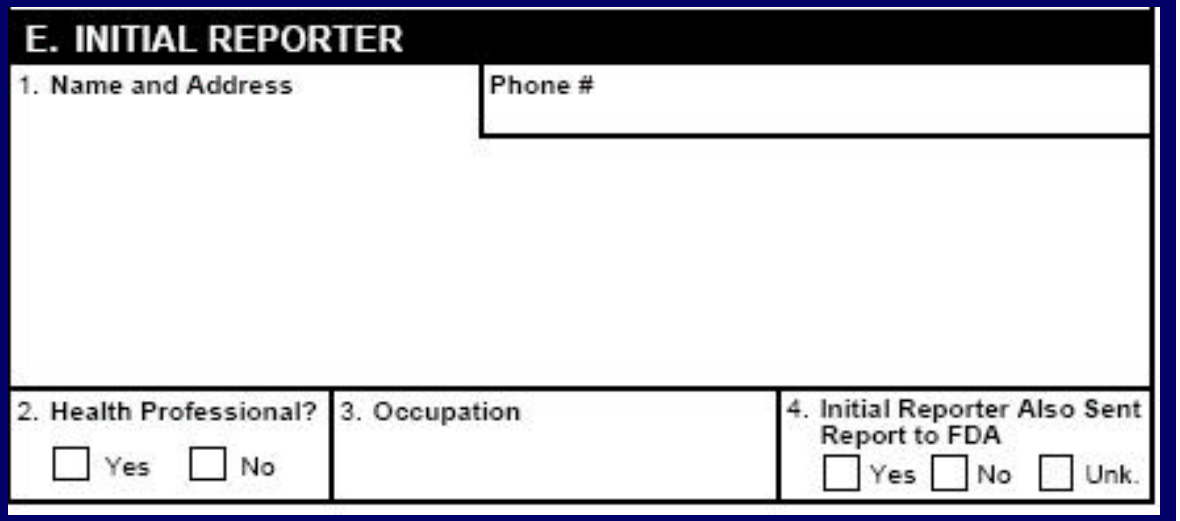
#2

9. **NDC # or Unique ID**

E. SUSPECT MEDICAL DEVICE

Section E.

Initial Reporter (who reported to you)



E. INITIAL REPORTER

1. Name and Address	Phone #

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☐ No		☐ Yes ☐ No ☐ Unk.

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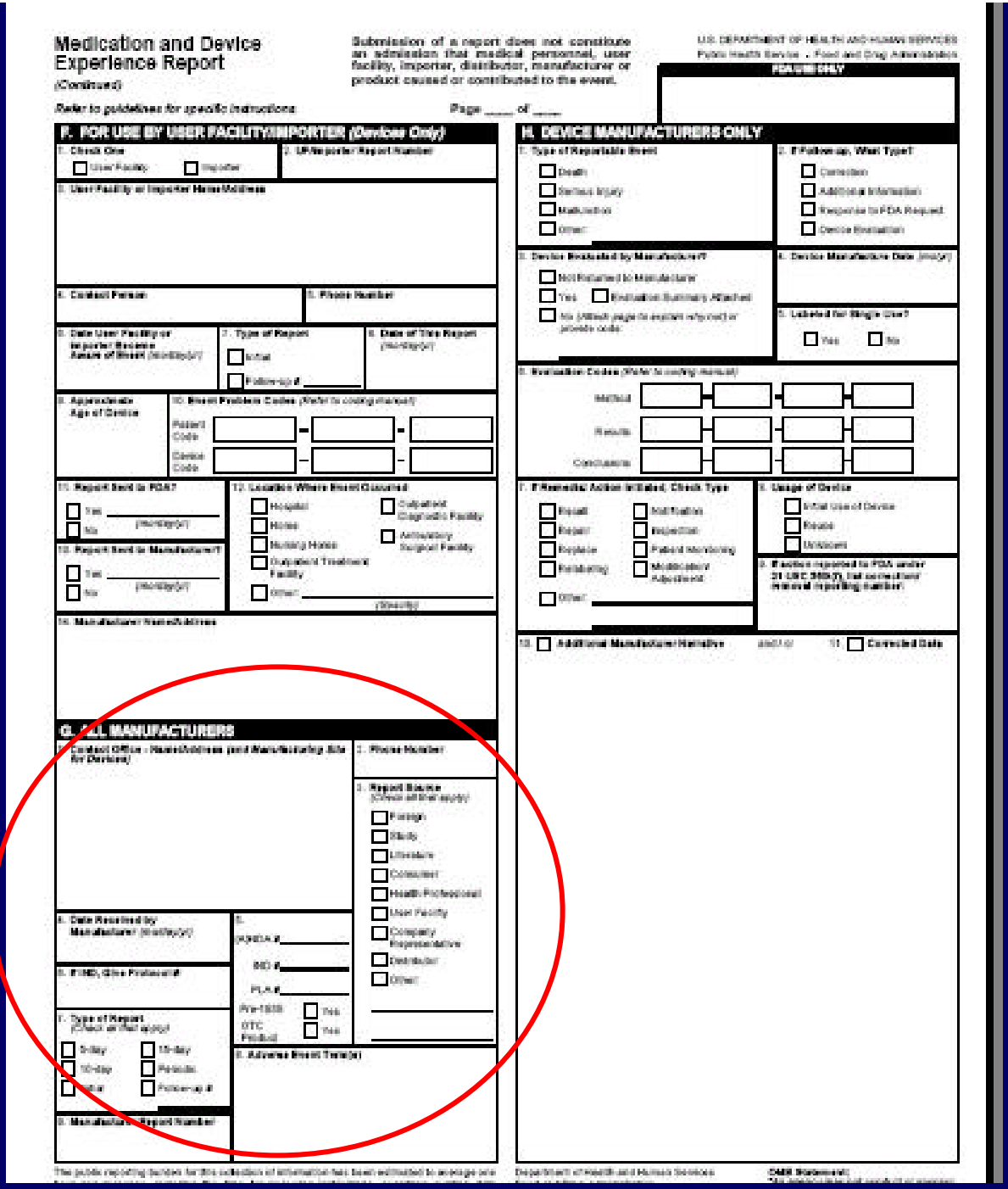
Page 2

Section F:
For Use by User Facility/Importer (Devices Only)

Section G:
All Manufacturers

Section H: Device Manufacturers

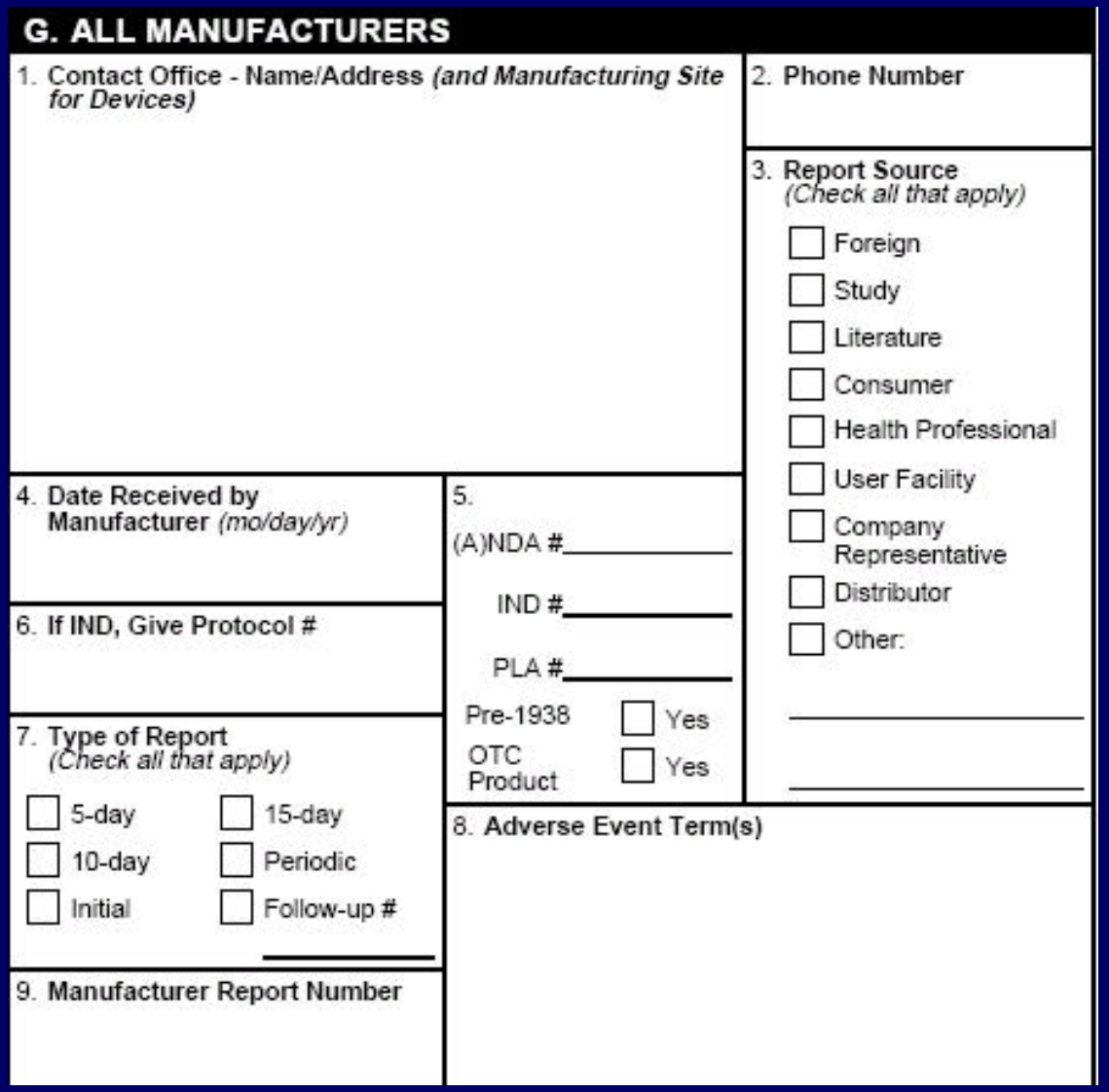


MedWatch Form
Form FDA 3500A

Page 2

Section G*

(Sections F and H are for device manufacturers)



G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

2. Phone Number

3. Report Source *(Check all that apply)*
- ☐ Foreign
- ☐ Study
- ☐ Literature
- ☐ Consumer
- ☐ Health Professional
- ☐ User Facility
- ☐ Company Representative
- ☐ Distributor
- ☐ Other:

4. Date Received by Manufacturer *(mo/day/yr)*

5.
(A)NDA #_____
IND #_____
PLA #_____
Pre-1938 ☐ Yes
OTC Product ☐ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
- ☐ 5-day
- ☐ 15-day
- ☐ 10-day
- ☐ Periodic
- ☐ Initial
- ☐ Follow-up # _____

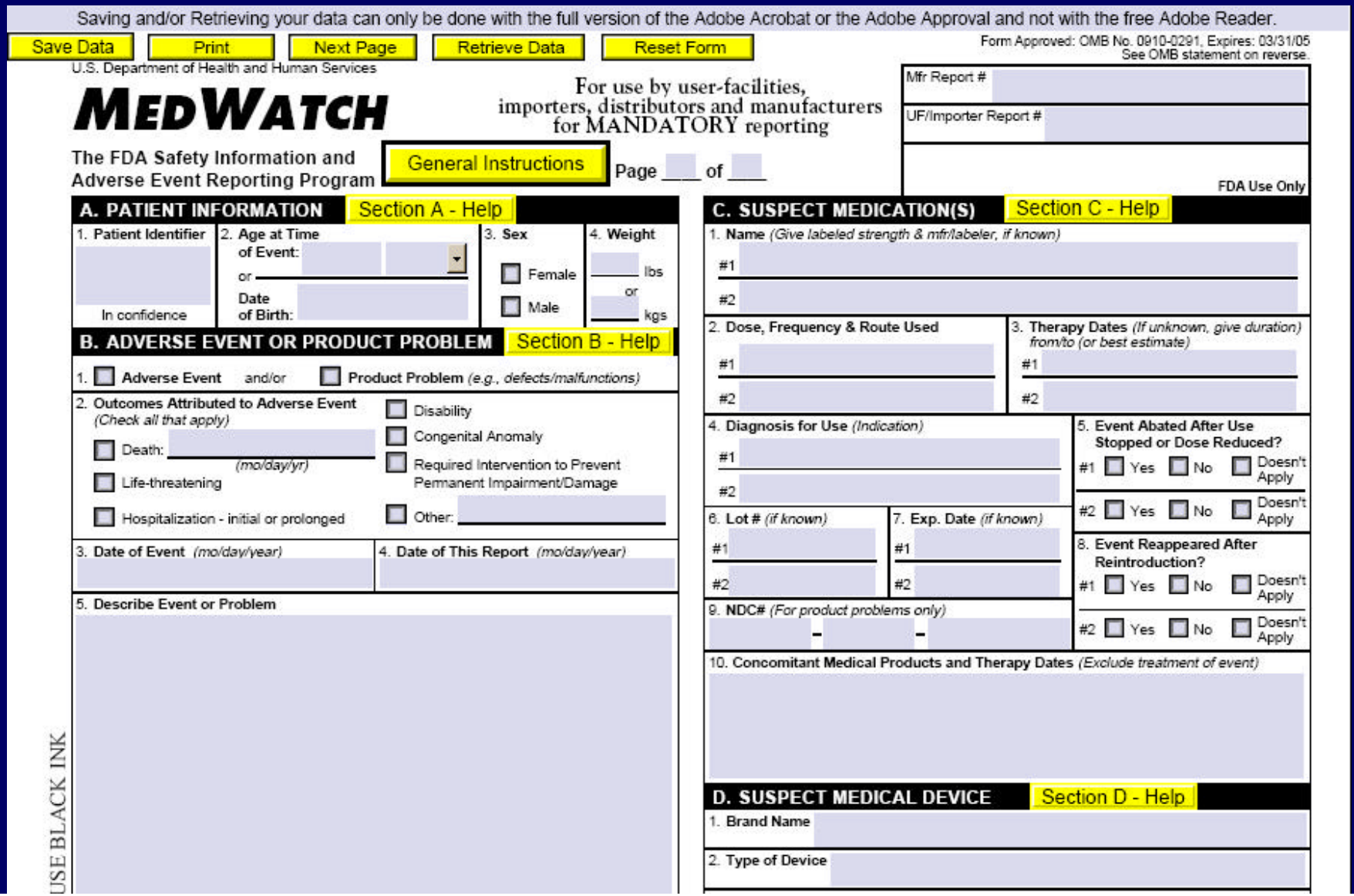
8. Adverse Event Term(s)

9. Manufacturer Report Number

* Will be Section I in the Revised 3500A

Filling out MedWatch on-line (fillable pdf)

http://www.fda.gov/medwatch/getforms.htm



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Save Data | Print | Next Page | Retrieve Data | Reset Form

Form Approved: OMB No. 0910-0291, Expires: 03/31/05
See OMB statement on reverse.

U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

General Instructions

Page ___ of ___

Mfr Report #

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION Section A - Help

1. Patient Identifier — In confidence
2. Age at Time of Event: or Date of Birth:
3. Sex — Female / Male
4. Weight — lbs or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM Section B - Help

1. Adverse Event and/or Product Problem *(e.g., defects/malfunctions)*
2. Outcomes Attributed to Adverse Event *(Check all that apply)*
   - Death: *(mo/day/yr)*
   - Life-threatening
   - Hospitalization - initial or prolonged
   - Disability
   - Congenital Anomaly
   - Required Intervention to Prevent Permanent Impairment/Damage
   - Other:
3. Date of Event *(mo/day/year)*
4. Date of This Report *(mo/day/year)*
5. Describe Event or Problem

C. SUSPECT MEDICATION(S) Section C - Help

1. Name *(Give labeled strength & mfr/labeler, if known)* #1 #2
2. Dose, Frequency & Route Used #1 #2
3. Therapy Dates *(If unknown, give duration from/to (or best estimate))* #1 #2
4. Diagnosis for Use *(Indication)* #1 #2
5. Event Abated After Use Stopped or Dose Reduced? #1 Yes No Doesn't Apply; #2 Yes No Doesn't Apply
6. Lot # *(if known)* #1 #2
7. Exp. Date *(if known)* #1 #2
8. Event Reappeared After Reintroduction? #1 Yes No Doesn't Apply; #2 Yes No Doesn't Apply
9. NDC# *(For product problems only)* – –
10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE Section D - Help

1. Brand Name
2. Type of Device

USE BLACK INK

Where do I submit the MedWatch form?

- **Send 2 copies of each MedWatch report to:**

  Center for Biologics Evaluation and Research

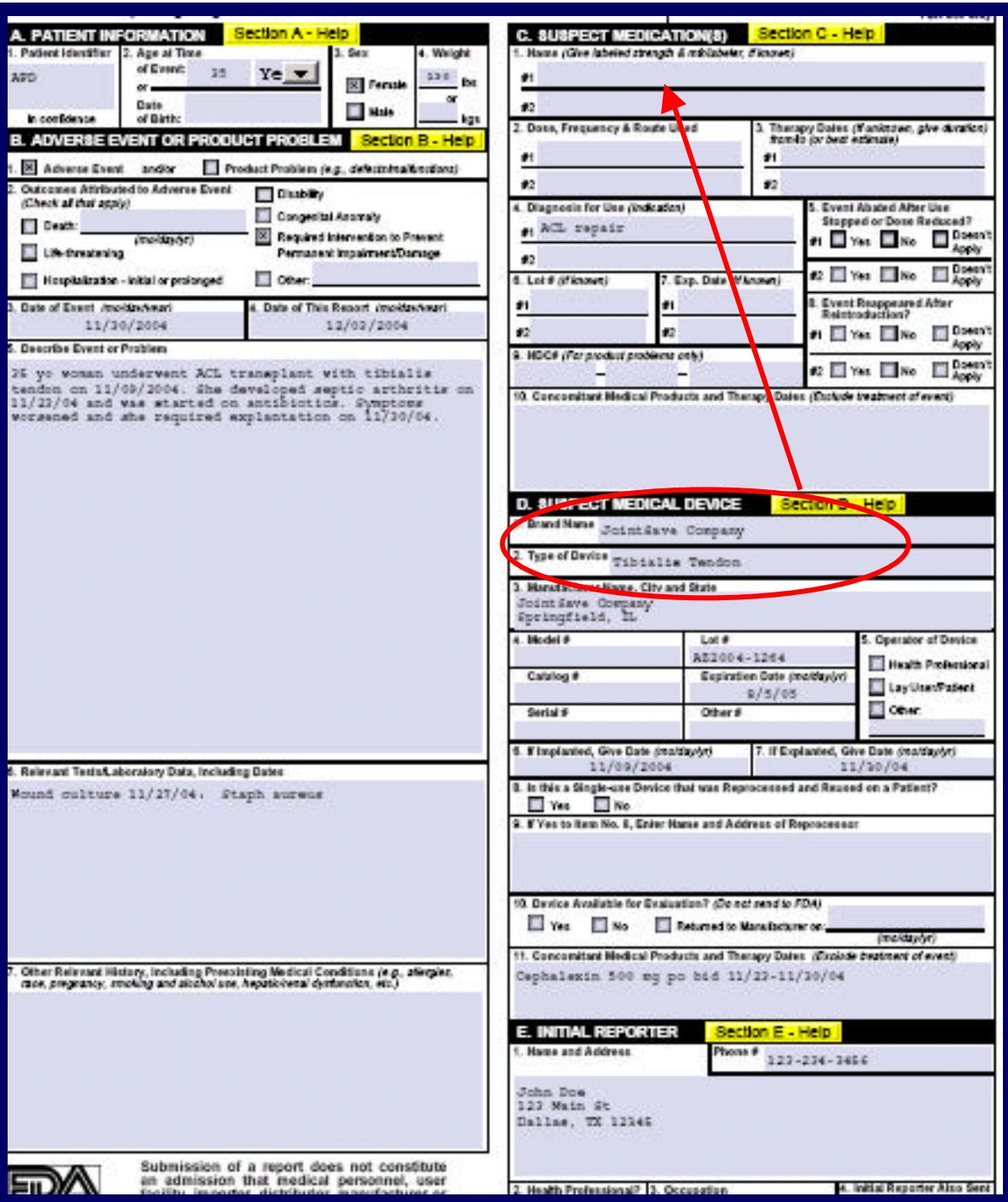
  HFM-210

  1401 Rockville Pike, Suite 200N

  Rockville, MD 20852

Common MedWatch Problems

Device Section filled out



A. PATIENT INFORMATION — Section A - Help

1. Patient Identifier: APD
2. Age at Time of Event: 25 Yr
or Date of Birth:
3. Sex: Female
4. Weight: 130 lbs or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM — Section B - Help

1. Adverse Event and/or Product Problem (e.g., defect/malfunction)
2. Outcomes Attributed to Adverse Event (Check all that apply)
Death: (mo/day/yr)
Life-threatening
Hospitalization - initial or prolonged
Disability
Congenital Anomaly
Required Intervention to Prevent Permanent Impairment/Damage
Other:
3. Date of Event (mo/da/year): 11/30/2004
4. Date of This Report (mo/da/year): 12/02/2004
5. Describe Event or Problem:
35 yo woman underwent ACL transplant with tibialis tendon on 11/09/2004. She developed septic arthritis on 11/22/04 and was started on antibiotics. Symptoms worsened and she required explantation on 11/30/04.
6. Relevant Tests/Laboratory Data, including Dates:
Wound culture 11/27/04. Staph aureus
7. Other Relevant History, including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or

C. SUSPECT MEDICATION(S) — Section C - Help

1. Name (Give labeled strength & manufacturer, if known)
#1
#2
2. Dose, Frequency & Route Used
3. Therapy Dates (If unknown, give duration) from/to (or best estimate)
4. Diagnosis for Use (Indication)
#1 ACL repair
#2
5. Event Abated After Use Stopped or Dose Reduced?
#1 Yes No Doesn't Apply
#2 Yes No Doesn't Apply
6. Lot # (if known)
7. Exp. Date (if known)
8. Event Reappeared After Reintroduction?
#1 Yes No Doesn't Apply
#2 Yes No Doesn't Apply
9. NDC# (For product problems only)
10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

D. SUSPECT MEDICAL DEVICE — Section D - Help

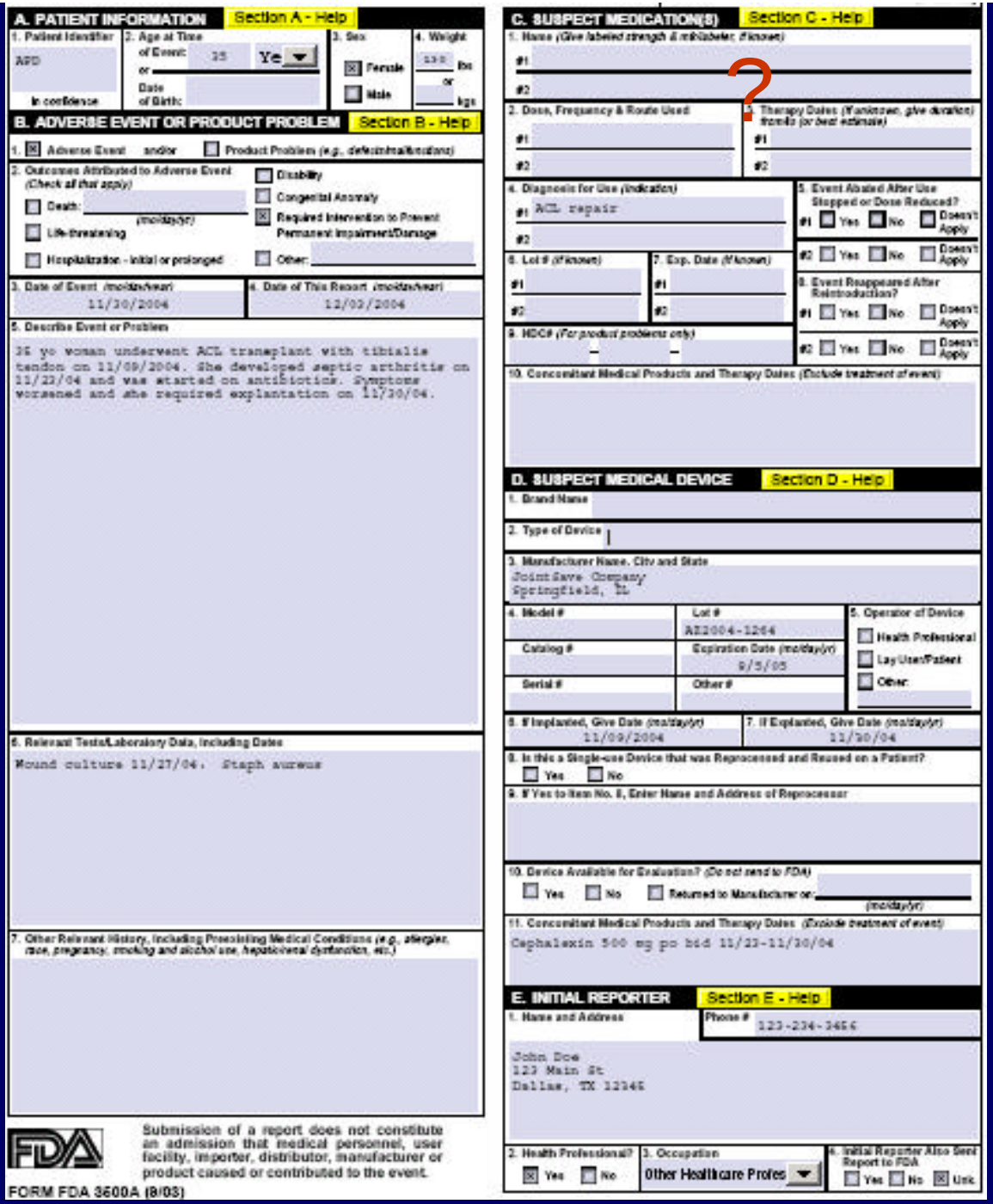
1. Brand Name: JointSave Company
2. Type of Device: Tibialis Tendon
3. Manufacturer Name, City and State:
JointSave Company
Springfield, IL
4. Model #
Lot # AE2004-1264
Catalog #
Expiration Date (mo/day/yr) 6/5/05
Serial #
Other #
5. Operator of Device
Health Professional
Lay User/Patient
Other:
6. If Implanted, Give Date (mo/day/yr): 11/09/2004
7. If Explanted, Give Date (mo/day/yr): 11/30/04
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
Yes No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor:
10. Device Available for Evaluation? (Do not send to FDA)
Yes No Returned to Manufacturer on: (mo/day/yr)
11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)
Cephalexin 500 mg po bid 11/23-11/30/04

E. INITIAL REPORTER — Section E - Help

1. Name and Address
Phone # 123-234-3456
John Doe
123 Main St
Dallas, TX 12345
2. Health Professional?
3. Occupation
4. Initial Reporter Also Sent

Common MedWatch Problems

No suspect product name



A. PATIENT INFORMATION — Section A - Help

1. Patient Identifier: APD — In confidence
2. Age at Time of Event: 35 Yr — or — Date of Birth:
3. Sex: Female / Male
4. Weight: 135 lbs — or — kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM — Section B - Help

1. Adverse Event and/or Product Problem (e.g., defect/malfunction)
2. Outcomes Attributed to Adverse Event (Check all that apply): Death (mo/day/yr); Life-threatening; Hospitalization - initial or prolonged; Disability; Congenital Anomaly; Required Intervention to Prevent Permanent Impairment/Damage; Other:
3. Date of Event (mo/da/year): 11/30/2004
4. Date of This Report (mo/da/year): 12/02/2004
5. Describe Event or Problem:

35 yo woman underwent ACL transplant with tibialis tendon on 11/09/2004. She developed septic arthritis on 11/23/04 and was started on antibiotics. Symptoms worsened and she required explantation on 11/30/04.

6. Relevant Tests/Laboratory Data, Including Dates:

Wound culture 11/27/04. Staph aureus

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

FDA — Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

FORM FDA 3500A (8/03)

C. SUSPECT MEDICATION(S) — Section C - Help

1. Name (Give labeled strength & manufacturer, if known):
#1
#2
?
2. Dose, Frequency & Route Used:
3. Therapy Dates (If unknown, give duration) from/to (or best estimate):
4. Diagnosis for Use (Indication):
#1 ACL repair
#2
5. Event Abated After Use Stopped or Dose Reduced? #1 Yes No Doesn't Apply; #2 Yes No Doesn't Apply
6. Lot # (if known):
7. Exp. Date (if known):
8. Event Reappeared After Reintroduction? #1 Yes No Doesn't Apply; #2 Yes No Doesn't Apply
9. NDC# (For product problems only):
10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event):

D. SUSPECT MEDICAL DEVICE — Section D - Help

1. Brand Name:
2. Type of Device:
3. Manufacturer Name, City and State:
Joint Save Company
Springfield, IL
4. Model #:
Lot #: AE2004-1264
Catalog #:
Expiration Date (mo/day/yr): 9/5/05
Serial #:
Other #:
5. Operator of Device: Health Professional; Lay User/Patient; Other:
6. If Implanted, Give Date (mo/da/yr): 11/09/2004
7. If Explanted, Give Date (mo/da/yr): 11/30/04
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? Yes No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor:
10. Device Available for Evaluation? (Do not send to FDA): Yes No Returned to Manufacturer on: (mo/day/yr)
11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event):

Cephalexin 500 mg po bid 11/23-11/30/04

E. INITIAL REPORTER — Section E - Help

1. Name and Address:
Phone #: 123-234-3456

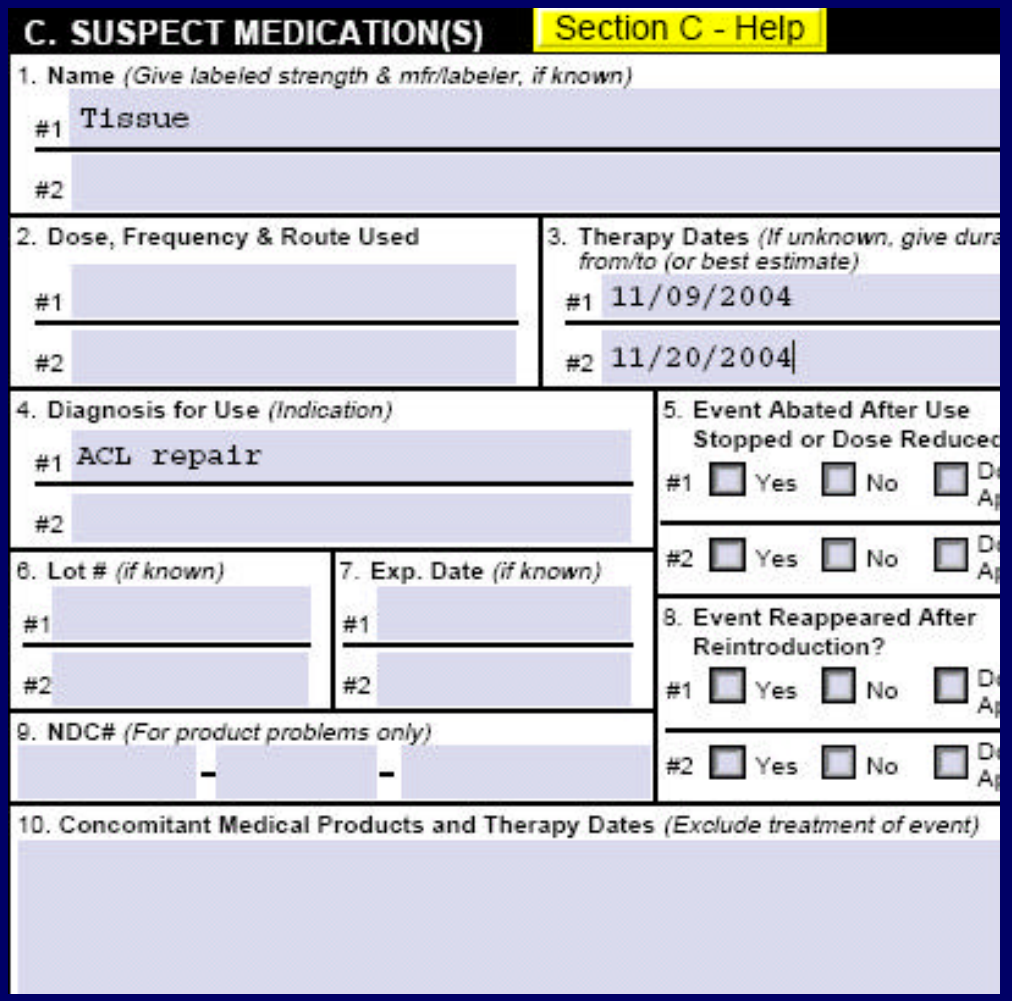
John Doe
123 Main St
Dallas, TX 12345

2. Health Professional? Yes No
3. Occupation: Other Healthcare Profes
4. Initial Reporter Also Sent Report to FDA: Yes No Unk

Common MedWatch Problems

Nonspecific product name

No manufacturer name



C. SUSPECT MEDICATION(S) Section C - Help

1. Name *(Give labeled strength & mfr/labeler, if known)*
#1 Tissue
#2

2. Dose, Frequency & Route Used
#1
#2

3. Therapy Dates *(If unknown, give dura from/to (or best estimate)*
#1 11/09/2004
#2 11/20/2004

4. Diagnosis for Use *(Indication)*
#1 ACL repair
#2

5. Event Abated After Use Stopped or Dose Reduced
#1 Yes No
#2 Yes No

6. Lot # *(if known)*
#1
#2

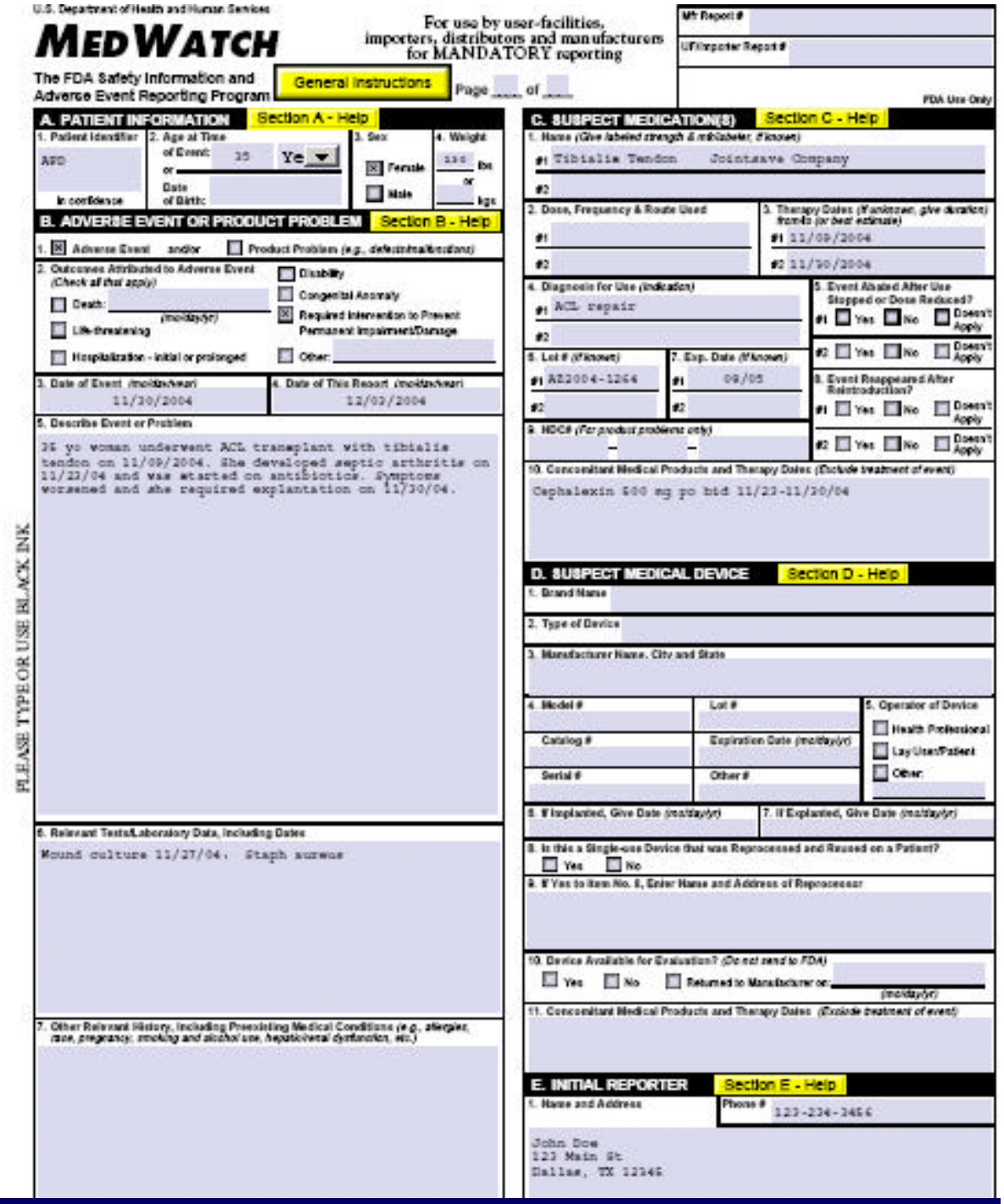
7. Exp. Date *(if known)*
#1
#2

8. Event Reappeared After Reintroduction?
#1 Yes No
#2 Yes No

9. NDC# *(For product problems only)*
- -

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

BRAVO!



U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

General Instructions

Page ___ of ___

Mfr Report #

U/Importer Report #

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION Section A - Help

1. Patient Identifier: ABD — In confidence
2. Age at Time of Event: 35 Yr — or Date of Birth:
3. Sex: [X] Female [ ] Male
4. Weight: 135 lbs — or ___ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM Section B - Help

1. [X] Adverse Event and/or [ ] Product Problem (e.g., defect/malfunction)
2. Outcomes Attributed to Adverse Event (Check all that apply)
   - [ ] Death: ___ (mo/day/yr)
   - [ ] Life-threatening
   - [ ] Hospitalization - initial or prolonged
   - [ ] Disability
   - [ ] Congenital Anomaly
   - [X] Required Intervention to Prevent Permanent Impairment/Damage
   - [ ] Other: ___
3. Date of Event (mo/day/year): 11/30/2004
4. Date of This Report (mo/day/year): 12/02/2004
5. Describe Event or Problem:

35 yo woman underwent ACL transplant with tibialis tendon on 11/09/2004. She developed septic arthritis on 11/23/04 and was started on antibiotics. Symptoms worsened and she required explantation on 11/30/04.

6. Relevant Tests/Laboratory Data, Including Dates:

Wound culture 11/27/04. Staph aureus

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

C. SUSPECT MEDICATION(S) Section C - Help

1. Name (Give labeled strength & manufacturer, if known):
   #1 Tibialis Tendon Jointsave Company
   #2
2. Dose, Frequency & Route Used:
   #1
   #2
3. Therapy Dates (If unknown, give duration) from/to (or best estimate):
   #1 11/09/2004
   #2 11/30/2004
4. Diagnosis for Use (Indication):
   #1 ACL repair
   #2
5. Event Abated After Use Stopped or Dose Reduced?
   #1 [ ] Yes [ ] No [ ] Doesn't Apply
   #2 [ ] Yes [ ] No [ ] Doesn't Apply
6. Lot # (If known):
   #1 AE2004-1264
   #2
7. Exp. Date (If known):
   #1 09/05
   #2
8. Event Reappeared After Reintroduction?
   #1 [ ] Yes [ ] No [ ] Doesn't Apply
   #2 [ ] Yes [ ] No [ ] Doesn't Apply
9. NDC# (For product problems only):
   – –
10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event):

Cephalexin 500 mg po bid 11/23-11/30/04

D. SUSPECT MEDICAL DEVICE Section D - Help

1. Brand Name
2. Type of Device
3. Manufacturer Name, City and State
4. Model # / Lot # / Catalog # / Expiration Date (mo/day/yr) / Serial # / Other #
5. Operator of Device: [ ] Health Professional [ ] Lay User/Patient [ ] Other:
6. If Implanted, Give Date (mo/day/yr)
7. If Explanted, Give Date (mo/day/yr)
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? [ ] Yes [ ] No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor:
10. Device Available for Evaluation? (Do not send to FDA) [ ] Yes [ ] No [ ] Returned to Manufacturer on: ___ (mo/day/yr)
11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event):

E. INITIAL REPORTER Section E - Help

1. Name and Address — Phone #: 123-234-3456

John Doe
123 Main St
Dallas, TX 12345